

12.13.99

WAYNE J. COLTON, INC.

Patent Prosecution ~ United States Patent and Trademark Office

The Milam Building Suite 1108  
115 East Travis Street  
San Antonio, Texas 78205

12/10/99  
JC542 U.S. PTO

A  
JC542 U.S. PTO  
09/458280  
12/10/99

Tel: (210) 222-8455  
Fax: (210) 222-8445

December 10, 1999

PATENT

Box Patent Application  
Assistant Comm'r for Patents  
Washington, D.C. 20231

RE: Invention Title      THERAPEUTIC APPARATUS FOR TREATING  
                                  ULCERS  
Serial Number      \*\*\*  
Filing Date      December 10, 1999  
Inventor(s)      Richard C. VOGEL *et al.*  
Docket Number      2000.1035

Dear Sir:

Enclosed herewith for filing in the above referenced matter, please find the following:

1. Application for Letters Patent;
2. Copy of Oath or Declaration under 37 CFR §1.63(d)(1);
3. Information Disclosure Statement;
4. Form PTO-1449 (with cited references); and
5. Addressed postcard to be returned upon receipt.

CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR §1.10)

"Express Mail" Mailing Label No: EL331367455US

Date of Deposit: December 10, 1999

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service, under 37 CFR §1.10, on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

12/10/99  
Date:

*Brian Goode*  
Signature of Person Mailing

Brian Goode  
Printed Name of Person Mailing

**WAYNE J. COLTON, INC.**

- [ ] No fee is required with this filing.
- [X] Please charge Deposit Account No. 50-0489 in the amount of \$ 760.00. **A COPY OF THIS LETTER IS ATTACHED.**
- [ ] The Commissioner has been authorized to charge the requisite fee to Deposit Account No. 50-0489.
- [ ] A check in the amount of \$ \*\*\* is enclosed herewith.

**GENERAL AUTHORIZATION TO CHARGE FEES:** The Commissioner is hereby authorized to charge any additional fee as may be required under 37 CFR §§1.16 and/or 1.17 at any time during the prosecution of the above referenced application, or credit any overpayment, to Deposit Account No. 50-0489, without further or more specific authorization.

Respectfully submitted,

Dated: 12/10/99

**WAYNE J. COLTON, INC.**  
The Milam Building Suite 1108  
115 East Travis Street  
San Antonio, Texas 78205  
Telephone: 210 222 8455  
Telecopier: 210 222 8445

  
Wayne J. Colton  
Agent for Applicant  
Registration No. 40,962

2000.1035

APPLICATION FOR LETTERS PATENT  
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Title: THERAPEUTIC APPARATUS FOR TREATING ULCERS

Inventors: Richard C. VOGEL  
David M. TUMEY  
Susan P. MORRIS  
L. Tab RANDOLPH

Assignee: KCI Licensing, Inc.  
8023 Vantage Drive  
San Antonio, Texas 78230

Filed By:

Wayne J. Colton  
Registration No. 40,962

Address for Correspondence:

**CUSTOMER NO. 22775**

Wayne J. Colton  
WAYNE J. COLTON, INC.  
The Milam Building Suite 1108  
115 East Travis Street  
San Antonio, Texas 78205  
Telephone: 210 222 8455  
Telecopier: 210 222 8445

CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR §1.10)

"Express Mail" Mailing Label No: EL331367455US

Date of Deposit: December 10, 1999

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service, under 37 CFR §1.10, on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

12/10/99  
Date:

*Brian Goode*  
Signature of Person Mailing

Brian Goode  
Printed Name of Person Mailing

## THERAPEUTIC APPARATUS FOR TREATING ULCERS

### RELATED APPLICATIONS:

This application claims, as a divisional application, priority under 35 USC §120 to co-pending application Serial No. 08/903,026 filed July 30, 1997, which claims under 35 USC §119(e) all available benefit of U.S. provisional patent application Serial No. 60/053,902 filed July 28, 1997. By this reference, the full disclosures, including the claims and drawings, of applications Serial No. 08/903,026 and 60/053,902 are incorporated herein as though now set forth in their respective entirety.

### FIELD OF THE INVENTION:

The present invention relates to methods and apparatus for treating foot ulcers. More particularly, the invention relates to methods and apparatus for applying positive and/or negative pressures to treat foot ulcers such as diabetic ulcers, arterial ulcers, venous stasis ulcers, pressure ulcers, and the like.

### BACKGROUND OF THE INVENTION:

Foot ulcers can be devastating – they are difficult to heal and are potentially limb-threatening. One of the difficulties is that a patient will often lose sensation in the area of an ulcer and, as a result, the patient tends to abuse the ulcer without notice. Foot ulcers, in particular, are troublesome because they are out of the patient's sight, especially when located on or near the patient's heel. Unseen and unfelt, the patient does not realize that the foot ulcer is colliding into a wheelchair, bedpost or the like. Consequently, the onset of a foot ulcer may place the foot at a significant risk for progression toward sepsis, gangrene and, ultimately, amputation.

Current treatment options for foot ulcers are varied, but all tend to be costly and traumatic; greater efficacy is thus desired. One of the most common treatment options is debridement of necrotic tissue followed by an attempt to physically close the ulcer, typically with sutures, skin grafts or the like. Unfortunately, many patients do not respond quickly, or at all, to such traditional treatment and the patient's condition often worsens. The resulting economic and emotional costs to the patient, and the patient's family, are staggering.

On the positive side, there have long been techniques available for promoting healthy circulation of body fluids. The concept of applying positive and/or negative pressure to help affect circulation is ancient, and many have sought to apply this concept to the foot in the form of inflatable boots that squeeze the foot and/or leg. Some have applied alternating positive and negative pressures, in a cyclic fashion, to first force blood out of the foot with positive pressure and then draw blood back into the foot with negative pressure. Recent products offered by Applicant under the trade designation "PLEXIPULSE" have provided intermittent compression, for a variety of indications, through pneumatic force externally applied to the foot. Such products are used, for example, to help prevent venous stasis and to promote circulation or to help treat and assist healing of cutaneous ulceration.

Another approach, for treatment of wounds, is represented by Applicant's products recently made commercially available under the trade designations "V.A.C." or "VACUUM ASSISTED CLOSURE." The "V.A.C." products generally comprise the application of negative pressure directly to a wound site, either on a continuous or intermittent basis. Such therapy units direct negative pressure to the wound site through a disposable pad, which includes a wound dressing and associated tubing, filters and drainage receptacles. The dressing itself includes a porous foam dressing sized to fit within the wound, the tubing directs the negative pressure into the foam, and the combination is sealed into the wound with the use of an adhesive drape that overlaps the entire wound site as well as a margin of surrounding intact skin. This therapy is

promising for treatment of pressure ulcers and chronic open wounds, including decubitus ulcers and diabetic ulcers.

Both of the above-described therapies are currently available as of the filing date of this present application; despite the availability of such progressive therapies, however, foot ulcers continue to present serious concerns for patients and caregivers. It is therefore a fundamental object of the present invention to advance upon the prior art by providing an improved method and apparatus for effecting intermittent pneumatic compression concurrently with vacuum assisted closure. Many additional problems, obstacles and challenges present in existing modalities for the treatment of foot ulcers will be evident to caregivers and others of experience and ordinary skill in the art.

#### SUMMARY OF THE INVENTION:

In accordance with the foregoing objects, the present invention – an improved method and apparatus for providing concurrent applications of intermittent pneumatic compression and vacuum assisted closure – generally comprises a wound dressing for introduction of a negative pressure into a wound on a patient's foot and a foot wrap for application of positive, compressive forces to substantially all of the patient's foot. A suction pump, having an associated vacuum sensor and first feedback mechanism, supplies negative pressure to the wound dressing. A ventable source of pressurized gas, having an associated pressure transducer and second feedback mechanism, supplies positive force to the foot wrap. At least one control system is operably associated with the suction pump and ventable source of pressurized gas for controlling the negative and positive applications of pressure to the patient's foot.

In preparation for operation, the wound dressing is preferably first applied to the patient's foot followed by application of the foot wrap. Each is then in turn operably connected to its respective pressure source. Specifically, for application of the wound dressing, a porous

pad, having plastic tubing inserted therein for connection to the suction pump, is inserted at least partially into the wound on a patient's foot. The wound dressing, and margin of impact surrounding the wound, is then preferably covered with a wound drape. The foot wrap, having fluid connection hardware associated therewith, is then placed in operable position over the wound dressing. Finally, the pad's plastic tubing is placed in fluid communication with the suction pump and the foot wrap's connection hardware is placed in fluid communication with the ventable source of pressurized gas.

In operation, negative pressure to the wound dressing is monitored and adjusted as necessary, by an integrated control system, to achieve desired therapy. Similarly, the positive, compressive force delivered to substantially the entire foot through the foot wrap is monitored and adjusted as necessary, also by an integrated control system, to achieve the desired therapy. Also effected by the integrated control system, the application timing of each component therapy is adjustable to allow concurrent application of pneumatic compression therapy and vacuum assisted closure therapy. It is to be understood that such concurrent therapy may entail continuous or intermittent application of one or both therapies and may or may not involve simultaneous application of the therapies.

Finally, many other features, objects and advantages of the present invention will be apparent to those of ordinary skill in the relevant arts, especially in light of the foregoing discussions and the following drawings, exemplary detailed description and appended claims.

#### BRIEF DESCRIPTION OF THE DRAWINGS:

Although the scope of the present invention is much broader than any particular embodiment, a detailed description of the preferred embodiments follows together with illustrative figures, wherein like reference numerals refer to like components, and wherein:

Fig. 1 illustrates, for reference purposes, regions 101–106 of a typical foot 100;

Fig. 2 shows, in a schematic block diagram, a first configuration 200 of the preferred embodiment of the present invention;

Fig. 3 shows, in perspective view, exemplary foot compression wraps 301, 302 as are utilized in the implementation of the preferred embodiment of the present invention;

5 Fig. 4 shows, in semi-perspective view, an exemplary wound closure dressing 402 and fluid reservoir 401 as are utilized in the implementation of the preferred embodiment of the present invention;

Fig. 5 shows, in a schematic block diagram, a second configuration 500 of the preferred embodiment of the present invention;

10 Figs. 6A and 6B illustrate, in plan view, application, as taught for implementation of the preferred embodiment of the present invention, of a wound closure dressing 402, 404 to a human foot 100;

Figs. 7A–7D illustrate, in perspective view, application, as taught for implementation of the preferred embodiment of the present invention, of a foot compression wrap 301, 302 to a human foot 100; and

15 Fig. 8 shows a wound closure dressing 404 and foot compression wrap 301 as simultaneously applied to a human foot 100 in implementation of the preferred embodiment of the present invention.

20 DETAILED DESCRIPTION OF PREFERRED EMBODIMENT:

By this reference, the full disclosures of Applicant's U.S. Patent Application Serial No. 08/039,574 filed March 23, 1993 and U.S. Patent Application Serial No. 08/517,901 filed August 22, 1995, are each incorporated herein as though set forth in their respective entireties. Copies of each of these applications are submitted herewith, through an accompanying Information Disclosure Statement, for entry into this application's file wrapper.

Although those of ordinary skill in the art will readily recognize many alternative embodiments, especially in light of the illustrations provided herein, this detailed description is exemplary of the preferred embodiments of the present invention, the scope of which is limited only by the claims appended hereto.

5 For reference purposes, various regions 101-106 of a typical foot 100 are shown in Fig. 1. Region 101 is referred to as the ankle region. Region 102 is referred to as the heel region. Region 103 is referred to as the plantar arch region. Region 104 is referred to as the metatarsal head, or ball, region. Region 105 is referred to as the toe region. Region 106 is referred to as part 10 of the dorsal aspect region. Although these regions are shown as being mutually exclusive, this representation is for purposes of illustration only. It should be understood that one region may overlap another. For example, reference to the heel region 102 is not necessarily confined to that region illustrated in the drawings; the reference may actually include the heel region 102 and overlapping portions of adjacent regions such as the ankle region 101 or plantar arch region 103. The same may be true of references to the metatarsal head 104, or other, regions. Ulcers may occur either centrally or on either side of the foot 100 in any of the regions 101-106 shown; however, clinical evidence has shown that ulcers are most prevalent in the heel region 102 and the forefoot beneath the metatarsal head region 104. A representative location 110 of an ulcer is designated with a dashed margin in Fig. 1, at the bottom of the heel region 102.

Fig. 8 illustrates a typical preferred application of the present invention for treating and 20 ulcer, or other wound, at ulcer location 110. Using the various apparatus and methods described further herein, localized negative pressure is induced on a foot 100 at the ulcer location 110 while positive, compressive force is applied to the foot 100. The resulting combination actively stimulates healing at the ulcer site 110 while also promoting healthy circulation of blood and nutrients.

Referring to Figs. 2–4, there is shown a first configuration 200 of a system for therapeutic treatment of foot ulcers such as that shown at the ulcer location 110. This first configuration generally comprises an efficient combination of previously available vacuum assisted closure and intermittent pneumatic compression technologies for concurrent application of positive and negative pressures to an affected foot. According to the first configuration 200 of the preferred embodiment, there is generally provided an intermittent pneumatic compression unit 201 and a vacuum assisted closure unit 202 in operable communication with a single embedded micro-controller unit 203. The micro-controller unit 203 may be implemented in any of a variety of hardware and/or software designs as will be apparent to those of ordinary skill in the relevant arts. As will be apparent herein, the micro-controller unit 203 provides a single point of feedback driven control for both the intermittent pneumatic compression unit 201 and the vacuum assisted closure unit 202.

The intermittent pneumatic compression unit 201 of the first configuration 200 generally comprises an oscillating air compressor 204 in fluid communication with an air reservoir 205 through a one-way check valve 206. As will be understood further herein, the check valve 206 serves to prevent pneumatic back flow from the air reservoir 205 to the oscillating air compressor 204 during periods in which the air compressor 204 is not in operation. The air reservoir 205 of the preferred embodiment is in fluid and operable communication with one or more foot compression wraps 301, 302 through a series of three-way solenoid valves 207-209, ports 210, 211, connectors 303, 304 and plastic, or other suitable material, tubing 305, 306.

Each of the solenoid valves 207–209 of the pneumatic compression unit 201 is chosen to be normally closed (when the coils are not energized) to the air reservoir 205 and normally open (when the coils are not energized) between the foot compression wraps 301, 302 and the atmosphere. When the coils are energized, atmosphere is closed off and a two-way pneumatic flow path is established between the air reservoir 205 and the foot compression wraps 301, 302.

Two of the solenoid valves 208, 209 are designated as the left foot solenoid valve 208 and the right foot solenoid valve 209. Through this designation, independent control is maintained for inflation of either the left foot compression wrap 301, the right foot compression wrap 302, or both 301, 302. As will be further understood herein, the third solenoid valve 207 is necessary only in an alternate embodiment of the present invention and, even then, may be dispensed with in implementations utilizing solenoid valves 208, 209 having a "no-flow" capability.

The vacuum assisted closure unit 202 of the first configuration 200 of the preferred embodiment generally comprises a vacuum pump 212 in fluid communication with a fluid reservoir 401 through a dryer filter 214. An intake vent 213 is provided for connection, through appropriate tubing 403, of a porous foam dressing 402 to be inserted into a patient's wound 110, as will be understood further herein. The dryer filter 214 serves to protect the vacuum pump 212, which is not readily decontaminated, from the potentially hazardous or infectious wastes drawn from the wound site 110. A port 215 is provided for releasable connection to the fluid reservoir 401 in order that the reservoir 401 may be removed and discarded when full.

Various sensors are provided to promote safety in the operation of the system 200. For example, a mercury activated tilt sensor 216 indicates attitudes in which there is a danger of spilling fluids from the reservoir 401, a push-button interlock switch 217 in the back of the reservoir port indicates improper or incomplete placement of the reservoir 401, and a capacitively-activated level sensor 218 indicates a full condition of the reservoir 401. Feedback from any of these sensors 217–219 will cause termination of vacuum pump 212 operation, as will be understood herein. Those of ordinary skill in the art will quickly recognize that many other safety features may be integrated into the system 200 as desired.

Further details as to the construction and operation of the intermittent pneumatic compression unit 201, including the foot compression wraps 301, 302, may be gleaned from Applicant's U.S. Patent Application No. 08/039,574 filed March 23, 1993 which has been

incorporated herein by reference. Details as to the construction and operation of the vacuum assisted closure unit 202 may be gleaned from Applicant's U.S. Patent Application No. 08/517,901 filed August 22, 1995 which also has been incorporated herein by reference. Those products embodying the foregoing applications, commercially available from Kinetic Concepts, Inc. of San Antonio, Texas under the trade designations "PLEXIPULSE" and "V.A.C." are presently preferred by Applicant for implementation of this present invention. It is to be understood, however, that many other intermittent pneumatic compression and vacuum assisted closure products, as well as products for sequential therapy, wound drainage and other related therapies, are also presently available. Most all of these products should be considered functional equivalents for implementation of this present invention.

According to the preferred embodiment of the present invention, there is provided a single embedded micro-controller unit 203 for operation of both the intermittent pneumatic compression unit 201 and the vacuum assisted closure unit 202. The micro-controller unit 203, intermittent pneumatic compression unit 201 and vacuum assisted closure unit 202 all receive electrical power through a conventional wall plug 219 fitted with a hospital grade EMI/RFI filter, fuse and switch unit 220. A power supply 222 is provided with the micro-controller unit 203 for conversion of alternating current to direct current at an appropriate voltage level for the integrated circuitry and displays 229, 230 present on the unit 203. The micro-controller unit 203 is fitted with a conventional variable speed cooling fan 221, as is known in the art.

Additionally, the micro-controller unit 203 is provided with a solenoid valve control circuit 223, a compressor control circuit 224, a vacuum pump speed control circuit 225, a vacuum pump control circuit 226, a pressure sensor 227 and a vacuum sensor 228. Each circuit 223-226 of the unit 203 is operatively connected, directly or indirectly, to the system components being controlled and to the various sensors 227, 228 upon which operation of the system components is based. In operation, the solenoid valve control circuit 223 opens or closes the left

and/or right solenoid valves 208, 209 according to a predetermined timing cycle in order to intermittently apply positive forces to substantially all, but in particular the plantar region 103, of the patient's foot 100.

In a preferred mode referred to as the "equilibrium mode," the oscillating air compressor 204 fills the air reservoir 205 to an automatically determinable target pressure, typically in the range of 350 mm Hg as measured by the pressure sensor 227. Once the pressure within the air reservoir 205 reaches the target pressure, the compressor 204 is shut off under the control of the compressor control circuit 224. Upon release of the compressed air into the left and/or right foot compression wraps 301, 302, an equilibrium pressure is reached between the air reservoir 205 and the wraps 301, 302. This equilibrium pressure, typically in the range of 160 mm Hg, is then measured by the pressure sensor 227 whereby an accurate indication of the actual pressure delivered to the plantar region arch 103 is obtained. The compressor control circuit 224 of the micro-controller unit 203 is then able to make use of this measurement to adjust, for subsequent compression cycles, the pressure of the air initially delivered to the air reservoir 205. Through this compression cycle-by-compression cycle adjustment scheme, the actual force applied to the patient's plantar region 103 may be robustly and accurately controlled, largely independent of wrap placement, changes in swelling or edema, or patient movements. Finally, at the end of the compression cycle and under the control of the solenoid valve control circuit 223, air is exhausted from the left and/or right foot compression wraps 301, 302, to the atmosphere, through the left and/or right solenoid valves 208, 209.

Alternatively, a third solenoid valve 207 may be incorporated to implement a timed-mode embodiment of the present invention. In this alternate embodiment, the oscillating air compressor 204 may operate continuously, the pressure ultimately delivered to the plantar regions 103 being controlled by the timed opening and closing of the third solenoid valve 207.

According to the timed-mode embodiment, the air reservoir 205 is filled to the extent of the air

compressor's capability, typically in the range of 800-900 mm Hg. Measurement of the initial pressure within the air reservoir is not necessary, so long as a relatively high pressure may be obtained within the capability of the air compressor 204. In operation, the solenoid valve control circuit 223 opens or closes the left and/or right solenoid valves 208, 209 in order to pre-select either the left or right foot, or both feet, for application of positive forces to the corresponding plantar regions 103. Substantially concurrent with the left and/or right foot selection, the solenoid valve control circuit 223 opens, for a short period of time, and then closes the third solenoid valve 207, causing a substantially impulsive burst of air to be released from the air reservoir 205 into the left and/or right foot compression wraps 301, 302. Following closure of the third solenoid valve 207, the pressure sensor 223 measures the pressure of the air released into the left and/or right foot compression wraps 301, 302. If necessary in order to achieve the desired compression wrap pressure, the open time of the third solenoid valve 207 may then be increased or decreased for subsequent compression cycles. Alternatively, the solenoid valve control circuit 223 may be implemented to produce only very short bursts of air from the air reservoir 205 into the foot compression wraps 301, 302. In this implementation, the number of bursts per compression cycle, and/or the time there between, may be increased or decreased during the present compression cycle, or in subsequent compression cycles, in response to the measured pressure in the foot compression wraps 301, 302. Like the equilibrium mode embodiment, the timed-mode embodiment provides a compression cycle-by-compression cycle adjustment scheme by which the actual force applied to the patient's plantar region 103 may be robustly and accurately controlled, largely independent of wrap placement, changes in swelling or edema, or patient movements. Finally, at the end of the compression cycle and under the control of the solenoid valve control circuit 223, air is exhausted from the left and/or right foot compression wraps 301, 302, to the atmosphere, through the left and/or right solenoid valves 208, 209.

In a further modification of the timed-mode embodiment, it is possible to dispense with the third solenoid valve 207 in favor of utilizing left and right solenoid valves 208, 209 having an intermediate “no-flow” capability. According to this modification, the left and right solenoid valves 208, 209 are normally closed (when the coils are not energized) between the foot compression wraps 301, 302 and both the air reservoir 205 and the atmosphere, i.e. are in a “no-flow” state. Short bursts of air are then delivered from the air reservoir 205 to the left and/or right foot compression wraps 301, 302, according to the foregoing timed-mode methods, by toggling the left and/or right solenoid valves 208, 209 between their no-flow states and their states of open flow between the air reservoir 205 and respective wrap 301, 302. At the end of the compression cycle, air is exhausted from the wraps 301, 302 by opening the flow paths to the atmosphere. Although technologically feasible, such solenoid valves are not as of this date readily available; therefore, the three-valve implementation of the timed-mode embodiment is presently preferred over the two-valve implementation of the timed-mode embodiment.

In further operation, the negative pressure induced by the vacuum pump 212 is measured by a vacuum sensor 228 in fluid communication with the fluid reservoir 401 through an interposed orifice restrictor 231. The restrictor 231 serves to protect the vacuum sensor 228 from the relatively large negative pressures necessary in the treatment process as these pressures are typically too excessive for direct measurement under presently available sensor technologies. Vacuum feedback is monitored by the vacuum pump control circuits 226 to adjust the speed, through the vacuum pump speed control circuit 225, of the vacuum pump’s motor in order to increase or decrease delivered vacuum. Additionally, the vacuum pump control circuit 226 monitors the various safety features 216–218 of the vacuum assisted closure unit 202 in order to effect shut down of the system 200 in the event of a hazardous condition.

Finally, all operations may be monitored through a liquid crystal display (LCD) readout 229 and/or light emitting diode (LED) display bar 230. Other feedback mechanisms, such as

computer interfaces and others known to those of ordinary skill in the art, may be incorporated as desired. All such user interfaces are considered within the scope of the present invention.

In a second configuration 500 of the preferred embodiment, shown in Fig. 5, the oscillating air compressor 204 and vacuum pump 212 are replaced by a single integrated 5 compressor and vacuum pump unit 501 having internally thereto two separate plenums 502, 203.

Operation is identical to that of the first configuration 200, with the exception that instead of speed control of the motors of the compressor 204 and vacuum pump 212, a clutch mechanism similar to that of automobile air conditioning units is utilized. Such mechanisms are readily understood by those of ordinary skill in the art. In essence, the appropriate control circuits 224, 10 225 generate pulse streams by which the respective clutch mechanisms are activated in pulse width modulated fashion.

Referring to Figs. 6A and 6B, there is shown the typical application of a wound closure dressing 402 to an example ulcer 110. Following debridement of necrotic tissue in and around the wound site 110, a porous foam dressing 402, having inserted therein tubing 403 for establishing fluid communication with the vacuum assisted closure unit 202, is inserted into the site 100. The porous foam dressing 402 and tubing 403 are anchored, and substantially sealed, within the wound site 110 by a covering of adhesive drape 404. The drape 404 physically covers the wound site 110 as well as the margin of impact 601 surrounding the wound site 110. A typical application, therefore, has a diameter of approximately four to eight inches, as measured 15 20 if the drape 404 was laid flat.

In operation, the vacuum assisted closure unit 202 applies negative pressure, through the tubing 403, to the ulcer site 110. The porous foam dressing 402 serves to promote distribution of this negative pressure throughout the ulcer site 110. As a result, this distribution may be considered substantially uniform. The adhesive drape 404, itself or in concert with such other provisions as may be implemented by caregivers, serves to provide a seal around the wound site 25

110. This seal provides infection control for the wound while also minimizing leaks of the negative pressures applied thereto.

Referring now to Figs. 7A–7D, there is shown the application of a foot compression wrap 301 to a foot 100. As shown particularly in Fig. 7A, the wrap 301 is first laid flat, generally beneath the heel, plantar arch and metatarsal head regions 102-104 of the foot 100. Then, as shown in Fig. 7B, a first tab 702 is wrapped about the dorsal aspect region 106 of the foot 100. A second tab 703, as shown in Fig. 7C, is next also wrapped about the dorsal aspect region 106 of the foot 100 and secured to the outside of the first tab 702 by conventional securing means such as, for example, releasably engageable hook and loop type material as is known by those of ordinary skill in the art and commercially available under the trademark “VELCRO.” In the preferred embodiment of the present invention, a trademark “VELCRO” type patch 704 of hook-type material engages the outer surface of the wrap 301 which comprises hook compatible loop-type material. Finally, as shown in Figs. 7C and 7D, a third tab 705 is wrapped about the ankle region 101 of the foot 100 and secured over the dorsal aspect region 106 by a tab 706 of hook-type material. As can be seen with reference to Figs. 7A–7D, it is a specific object of such a foot compression wrap to cover a substantial portion of the foot with the inflatable bladder 701 integral thereto. In accordance with this object, both the deep and peripheral veins in the foot are compressed by operation of the intermittent pneumatic compression unit 201. This enables virtually complete emptying, on an intermittent basis, of the blood in the foot 100 to which the wrap 301, 302 is applied.

As clearly shown in Fig. 8, depicting the foot 100 with both the porous wound dressing 402, with drape 404, and the foot compression wrap 301 in operable position, portions of the heel region 102 and toe region 105 are not covered by the foot compression wrap 301 notwithstanding the object of compressing substantially the entire foot 100. This serves to enable viewing, by caregivers, of the exposed portions of the toe region 105 and heel region 102 for purposes of

assessing the health of the foot 100 while the foot compression therapy is ongoing. This also readies skin on the foot 100 to minimize accumulation of moisture and the attendant risks of maceration.

In implementing the present invention, the wound closure dressing 402, 404 is applied first, in its entirety, and then the foot compression wrap 301 is applied. Due to the varying locations of ulcers on the foot 100, application of the foot compression wrap 301 may overlap the wound dressing site 601. Many applications within the scope of the present invention will also involve lapping the inflatable bladder 701 of the foot compression wrap 301 over the actual ulcer site 110. In such applications, the foam dressing 402 also serves the added function of helping to cushion the actual ulcer site 110 from the compressive action of the foot compression wrap 301. As shown in Fig. 8, the foot compression wrap 301 may overlap a portion of the ulcer site 110 to an extent that the inflatable bladder of the foot compression wrap 301 applies a compressive force over and onto the ulcer site 110.

Once the wound closure dressing 402 is operatively situated on an ulcer site 110 on the foot 100 of the patient and the foot compression wrap 301 or 302 is applied over the wound closure dressing 402 and its drape 404, the foot compression wrap 301 is then operatively connected to the intermittent pneumatic compression unit 201 and the wound dressing 402 is operatively connected to the vacuum assisted closure unit 202. Vacuum assisted closure therapy and intermittent pneumatic foot compression therapy can then be concurrently implemented, i.e., either simultaneously or in some indefinitely repeated cycle between positive and negative applications during which, it is to be understood, temporal overlap of positive and negative applications may or may not occur.

In the preferred embodiment of the present invention, the vacuum assisted closure unit 202 is provided with various settings for both intermittent and continuous application of negative pressure to the wound closure dressing 402. The most preferred selection of therapy options, i.e.,

intermittent or continuous vacuum, has not been determined at this time, although it is contemplated that either setting may be applicable. In any case, typical implementation of the invention will involve some periods of time during which negative pressure is actually applied to the ulcer site 110 notwithstanding the substantially concurrent application of compressive forces  
5 via the foot compression wrap 301, 302.

In a second mode of application of the present invention, the applications of positive and negative pressures are timed such that negative pressure is applied to the ulcer site 110 over a first period of time and positive pressure is then applied to substantially the entire foot 100 over a second period of time. Such alternating applications of negative pressure and positive pressure over the corresponding regions of the foot are then repeated indefinitely for the duration of the  
10 therapy.

While the foregoing description is exemplary of the preferred embodiments of the present invention, those of ordinary skill in the relevant arts will recognize the many variations, alterations, modifications, substitutions and the like as are readily possible, especially in light of this description, the accompanying drawings and claims drawn thereto. For example, while the preferred embodiment of the present invention calls for implementation of the intermittent pneumatic compression unit 201 and the vacuum assisted closure unit 202 in a single integrated unit 200, 500, those of ordinary skill in the art will recognize that, in the alternative, the present invention may be practiced, with only some corresponding loss in efficiency, with separate units  
15 for provision of intermittent compression therapy and vacuum assisted closure therapy. Such individual units are readily available and exemplary ones are described in detail in U.S. Patent Application Serial No. 08/039,574 filed March 23, 1993 and U.S. Patent Application Serial No. 08/517,901 filed August 22, 1995, each of which has been incorporated herein by reference.  
20 Products embodying each of these applications are commercially available from Kinetic Concepts, Inc. of San Antonio, Texas under the trade designations "PLEXIPULSE" and  
25

“V.A.C.” In such an alternate embodiment, calling for separate therapy units, synchronization of the therapy timing may be provided by interface circuitry, manual adjustment of the individual units or any number of other techniques readily available to those of ordinary skill in the relevant arts. Further, other modifications, such as the provision of independent, switched control of the 5 intermittent pneumatic compression unit 201 and vacuum assisted closure unit 202 within the single integrated unit 200, 500, should be considered design expedients, within the scope of the present invention, especially in light of the foregoing exemplary description and appended claims. In any case, because the scope of the present invention is much broader than any particular embodiment, the foregoing detailed description should not be construed as a limitation 10 of the scope of the present invention, which is limited only by the claims appended hereto.

PCT/US2019/033860

CLAIMS:

We claim:

1. A medical apparatus for therapeutic treatment of foot ulcers, comprising:
  - 5 a wound dressing for introduction of a negative pressure over a first region of a patient's foot including a wound;
    - a foot wrap having an inflatable bladder for applying a compressive force over a second region of said patient's foot, concurrent with the introduction of said negative pressure, to compress veins of said patient's foot and thereby partially empty said veins;
    - 10 a negative pressure source for supplying negative pressure to said wound dressing; and
    - a positive pressure source for supplying compressive force to said foot wrap.
2. The medical apparatus of claim 1, wherein at least some part of said foot wrap overlaps at least some part of said wound dressing such that at least a portion of said second region overlaps said first region.
  - 15
3. The medical apparatus of claim 1, wherein at least some part of said foot wrap overlaps at least some part of said wound dressing such that at least a portion of said second region overlaps said wound.
  - 20
4. The medical apparatus of claim 1, wherein:
  - 25 at least a portion of said wound dressing comprises elastically compressible foam overlapping said wound; and
  - at least some part of said foot wrap overlaps at least some part of said wound dressing such that said second region overlaps said foam.

5. The medical apparatus of claim 1, wherein:

said negative pressure source comprises a suction pump; and

said positive pressure source comprises a ventable source of pressurized gas.

5 6. The medical apparatus of claim 5, further comprising a control system for defining the negative application of pressure to said wound dressing and the positive application of force to said foot wrap.

7. The medical apparatus of claim 6, wherein said negative application of pressure aspect of  
10 said control system comprises:

a vacuum sensor for measuring the negative pressure supplied to said wound dressing;

and

a first feedback mechanism for controlling, responsive to said measured negative pressure, said suction pump.

15 8. The medical apparatus of claim 6, wherein said positive application of pressure aspect of  
said control system comprises:

a pressure transducer for measuring the positive force supplied to said foot wrap; and

a second feedback mechanism for controlling, responsive to said measured positive

20 force, the venting of said source of pressurized gas into said foot wrap.

9. The medical apparatus of claim 6, wherein:

    said suction pump and said ventable source of pressurized gas comprise a single integrated compressor and vacuum pump unit; and

    said control system controls said integrated compressor and vacuum pump unit responsive to both negative pressure supplied to said wound and positive force supplied to said foot wrap.

10. An apparatus for treatment of ulcers located on the heel or metatarsal head regions of a foot, comprising:

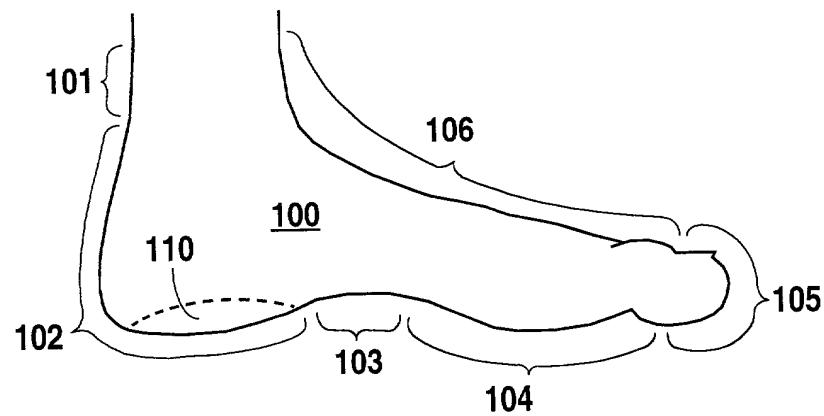
    a dressing for applying a negative pressure to the heel or metatarsal head regions of a foot; and

    a compressive element for applying a positive compressive force to a compressible region of the foot including the plantar arch region.

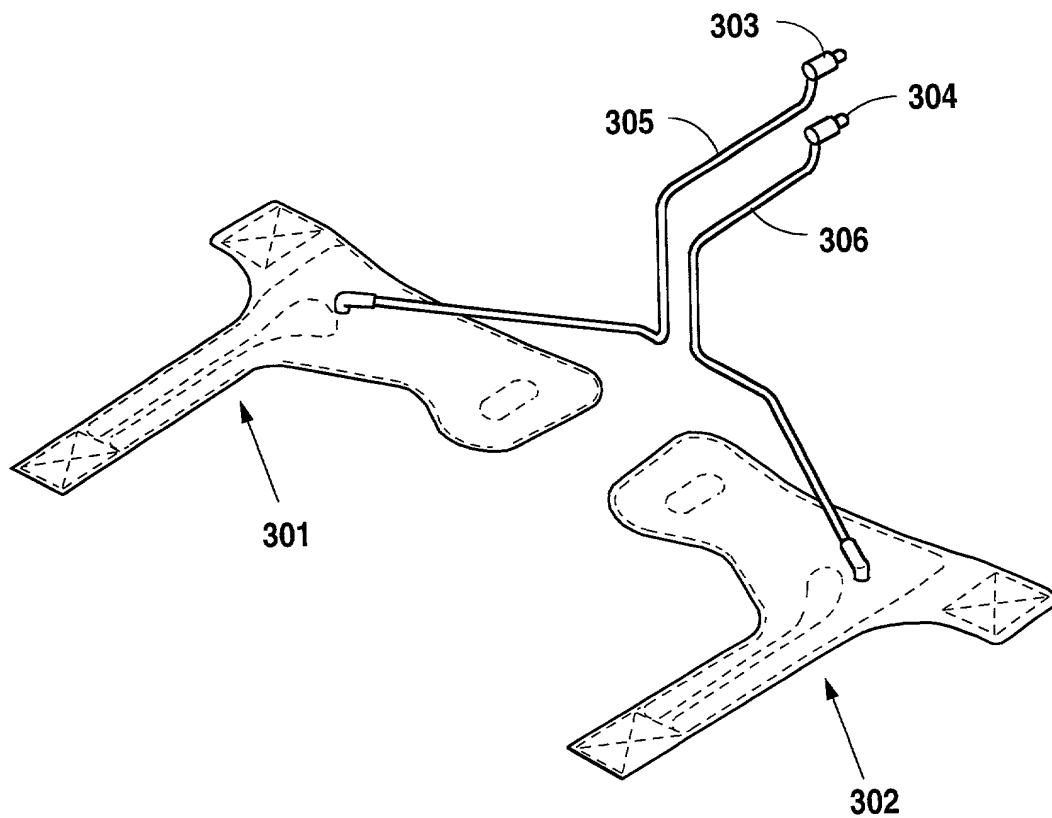
ABSTRACT OF THE DISCLOSURE:

A method and apparatus for providing concurrent applications of intermittent pneumatic compression therapy and vacuum assisted closure therapy generally comprises a wound dressing for introduction of a negative pressure into a wound on a patient's foot and a foot wrap for application of positive, compressive forces to substantially all of the patients foot. A suction pump, having an associated vacuum sensor and first feedback mechanism, supplies negative pressure to the wound dressing. A ventable source of pressurized gas, having an associated pressure transducer and second feedback mechanism, supplies positive force to the foot wrap. At least one control system is operably associated with the suction pump and ventable source of pressurized gas for controlling the negative and positive applications of pressure to the patient's foot. Controlled modes for operation include continuous or intermittent application of one or both therapies and simultaneous or cycled application of the therapies.

10

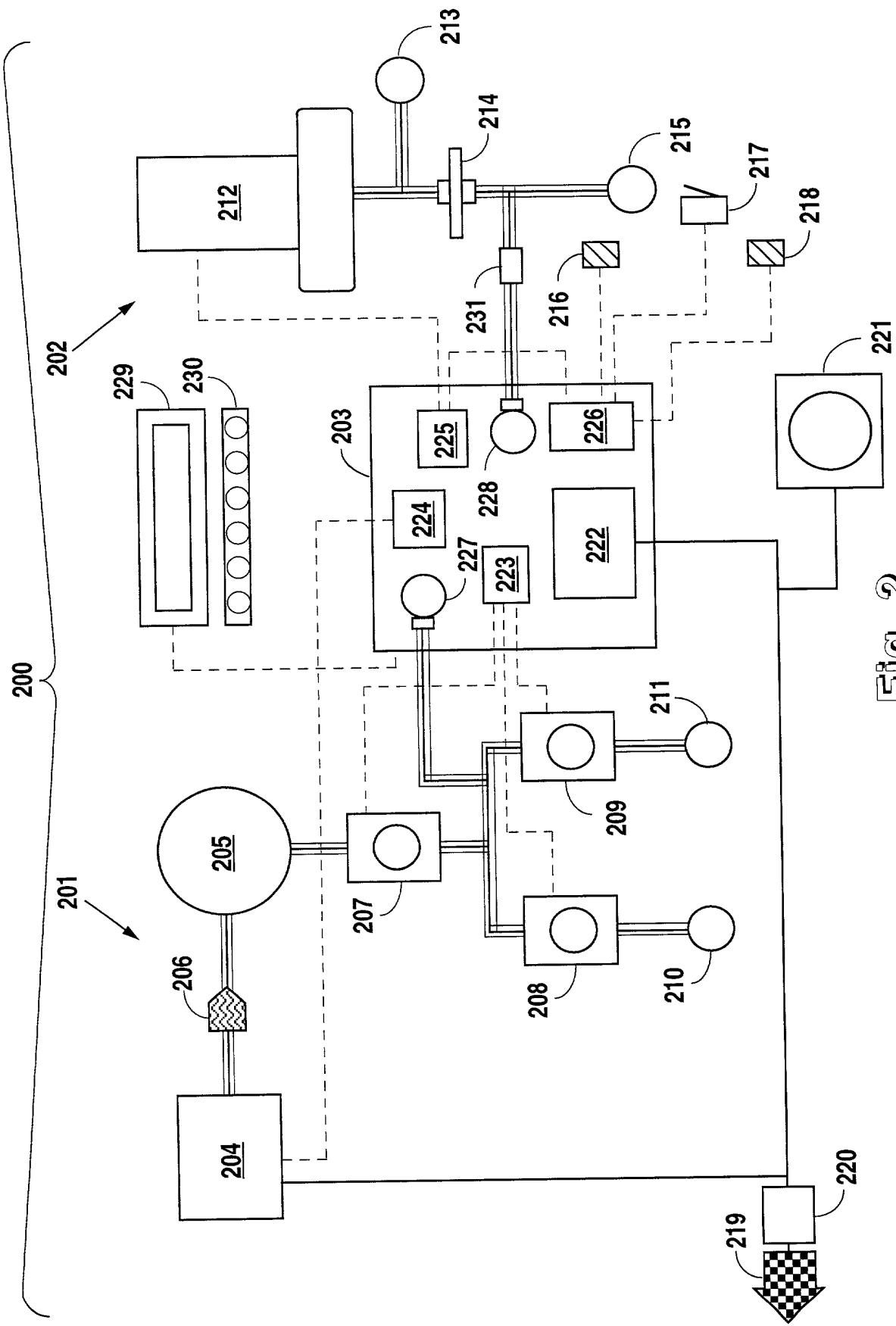


**Fig. 1**



**Fig. 3**

Fig. 2



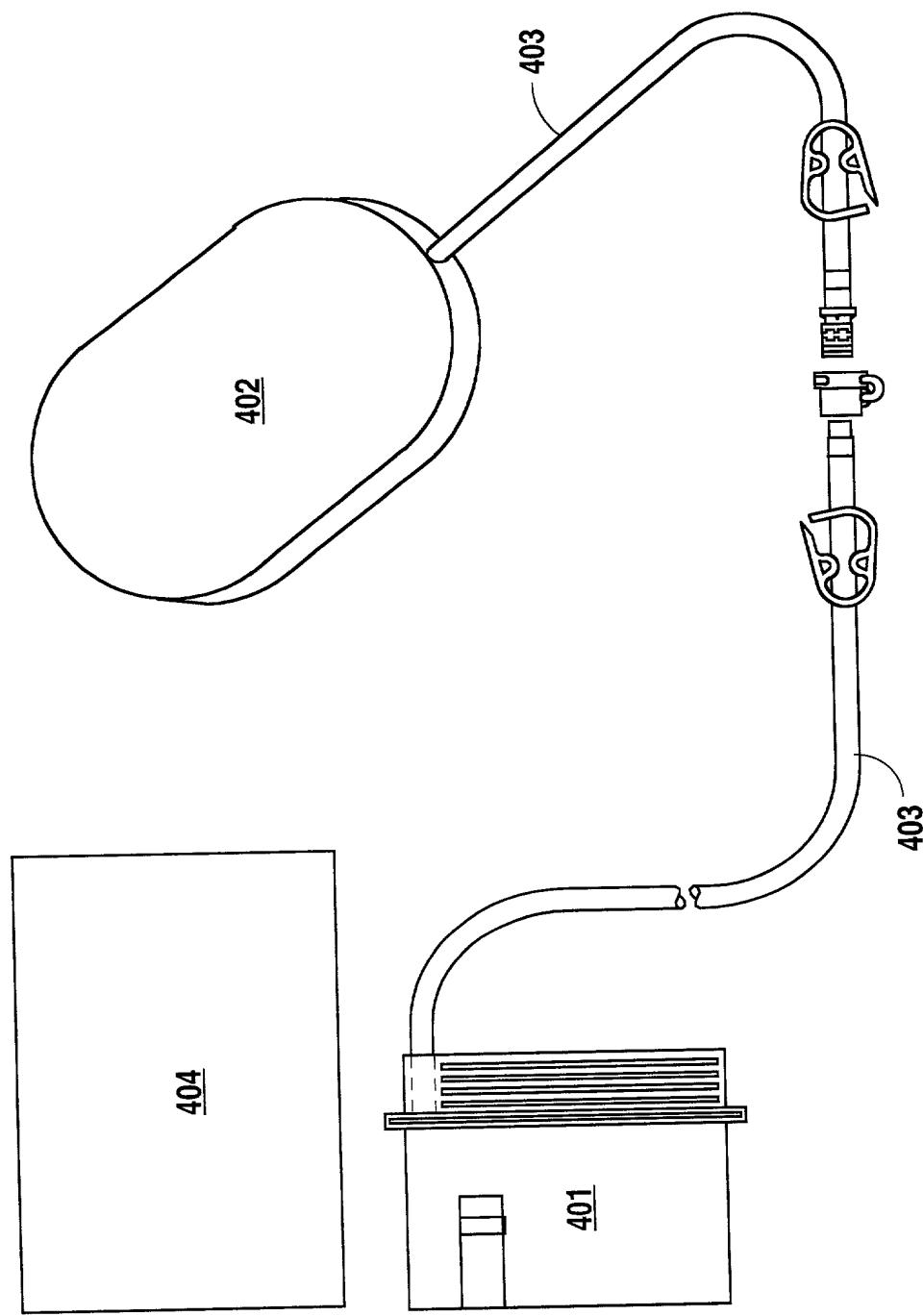
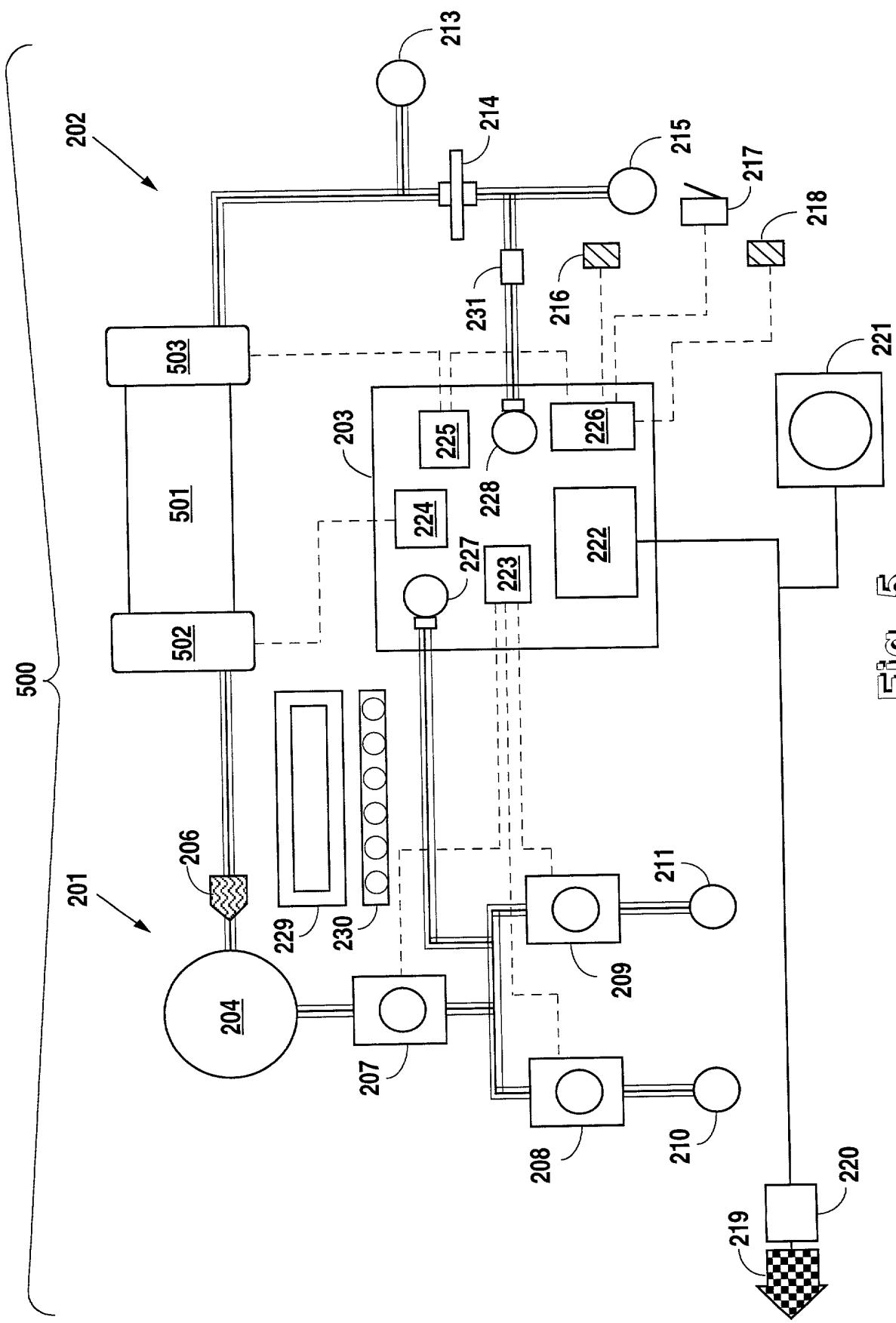
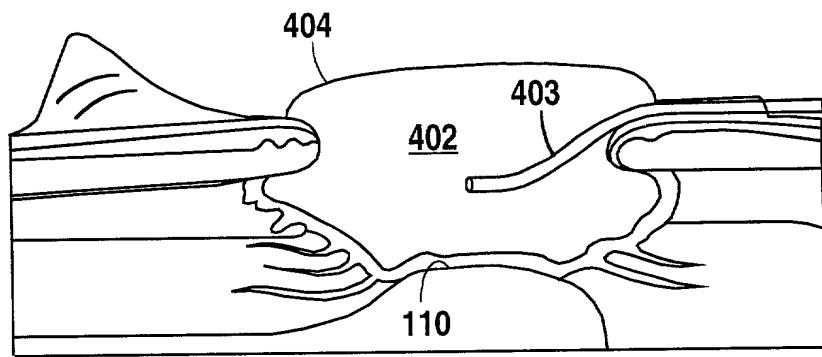


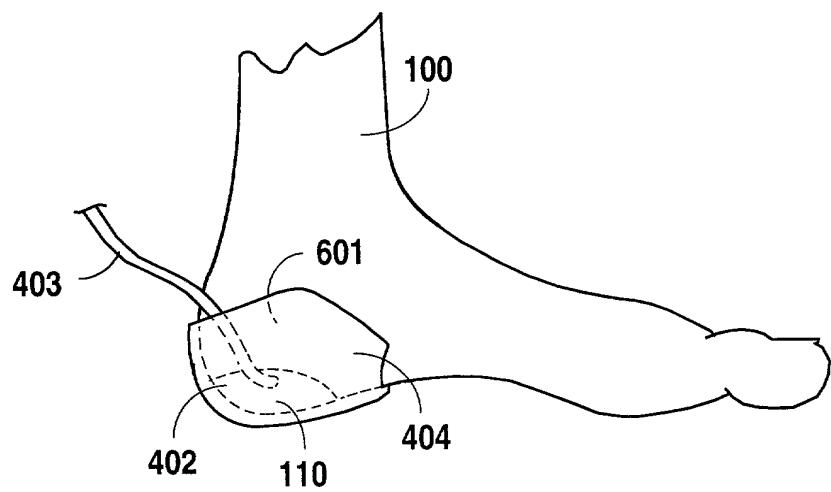
Fig. 4

Fig. 5

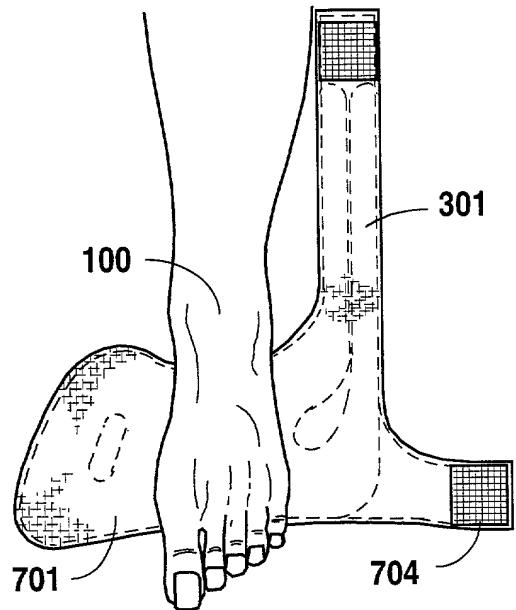




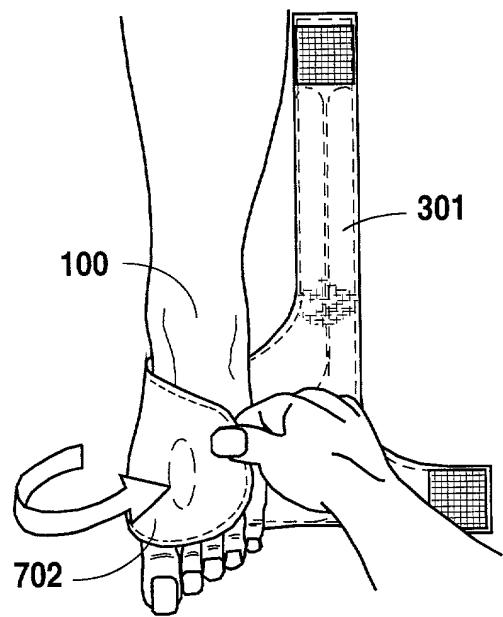
**Fig. 6A**



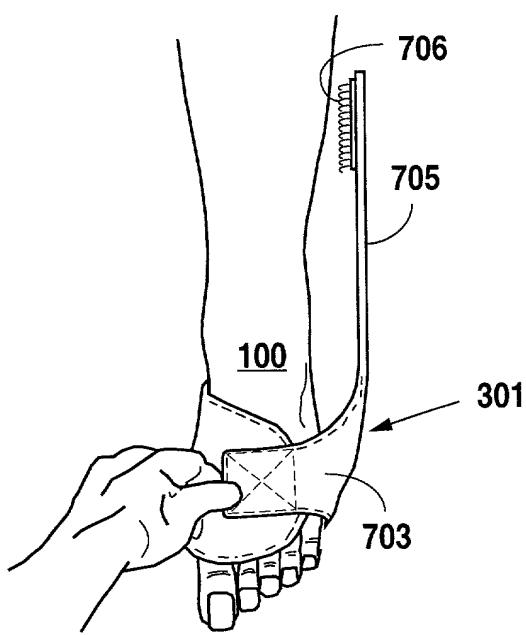
**Fig. 6B**



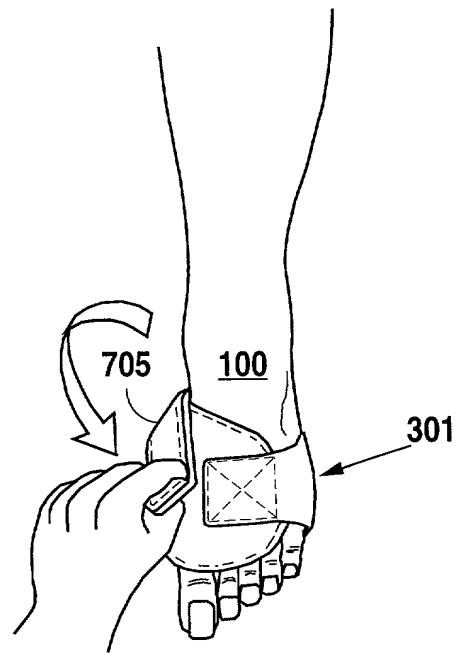
**Fig. 7A**



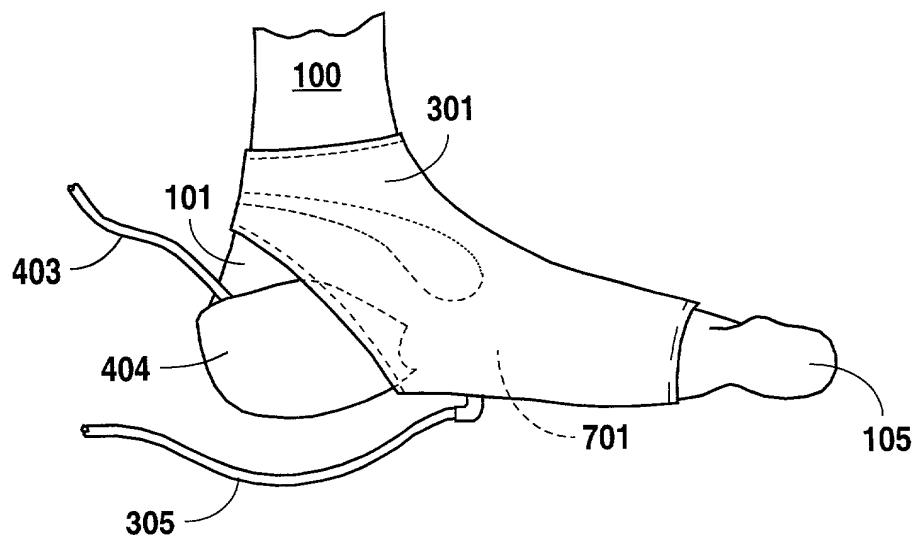
**Fig. 7B**



**Fig. 7C**



**Fig. 7D**



**Fig. 8**

2000.1035  
PATENT

**JN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Richard C. VOGEL *et al.*

Serial No.: \*\*\*

Filed: December 10, 1999

Title: THERAPEUTIC APPARATUS FOR  
TREATING ULCERS

**COPY OF OATH OR DECLARATION UNDER 37 CFR §1.63(d)(1)**

Box Patent Application  
Asst. Comm'r for Patents  
Washington, D.C. 20231

Sir:

Applicant respectfully requests acceptance of the accompanying declaration, submitted in accordance with the procedures of 37 CFR §1.63(d)(1), in fulfillment of the oath or declaration requirements of 37 CFR §§1.53(b) or (f) for the above-captioned application.

CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR §1.10)

"Express Mail" Mailing Label No.: EL331367455US

Date of Deposit: December 10, 1999

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service, under 37 CFR §1.10, on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Date:

Signature of Person Mailing

Brian Goode

Printed Name of Person Mailing

## REMARKS

*Parent Application and Inventorship:*

The above-captioned application is a

- ( ) continuation  
(X) divisional

of U.S. patent application Serial No. 08/903,026 filed July 30, 1997, ("the 'prior application'") which contained an oath or declaration as prescribed by 37 CFR §§1.63(a) through (c), and is filed by

- (X) all of the inventors named in the prior application.  
( ) fewer than all of the inventors named in the prior application. Please delete the name(s) of the following person(s):

\*\*\*

*Prior Oath or Declaration:*

A copy of the oath or declaration as executed and filed in the prior application

- (X) is submitted herewith.  
( ) will be submitted in accordance with 37 CFR §1.53(f).

*Status under 37 CFR §1.47:*

- (X) The prior application was not accorded status under 37 CFR §1.47.  
( ) The prior application was accorded status under 37 CFR §1.47 and the copy of the oath or declaration for the prior application is or will be accompanied by:
- ( ) a copy of the decision granting a petition to accord 37 CFR §1.47 status to the prior application.  
( ) a copy of the decision granting a petition to accord 37 CFR §1.47 status to the prior application and a copy of the subsequently executed oath(s) and/or declaration(s) of the following inventor(s) who subsequently joined in the prior application or another application to which the above-referenced application claims a benefit under 35 USC §§120, 121 or 365(c):

\*\*\*

*Power of Attorney (or Authorization of Agent):*

The power of attorney (or authorization of agent)

- (X) was not changed in the prior application.  
( ) was changed in the prior application in papers filed on \*\*\*. Please recognize the following person(s) as attorney and/or agent of record in the above-captioned application:

\*\*\*

*Correspondence Address:*

The correspondence address

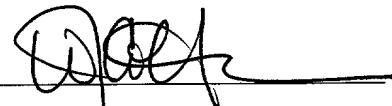
- ( ) was not changed in the prior application.  
(X) was changed in prior application in papers filed on January 8, 1999. Please send all correspondence and direct all telephone calls to **CUSTOMER NO. 22775** at:

Wayne J. Colton  
**WAYNE J. COLTON, INC.**  
The Milam Building Suite 1108  
115 East Travis Street  
San Antonio, Texas 78205

Telephone: 210 222 8455  
Telecopier: 210 222 8445

Respectfully submitted,

Dated: 12/10/99  
**WAYNE J. COLTON, INC.**  
The Milam Building Suite 1108  
115 East Travis Street  
San Antonio, Texas 78205  
Telephone: 210 222 8455  
Telecopier: 210 222 8445

  
Wayne J. Colton  
Agent for Applicant  
Registration No. 40,962

DECLARATION

As a below named inventor, I hereby declare that:

This declaration is of the following type:

- (X) original  
( ) design  
( ) supplemental  
( ) national stage of PCT

My residence address, post office address, and citizenship are as stated below next to my name, and I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

"THERAPEUTIC METHOD AND APPARATUS FOR TREATING ULCERS"

the specification of which:

- (X) is attached hereto.  
( ) was filed on \*\*\* as Application Serial No. \*\*\* and was amended on \*\*\* (if applicable).  
( ) was described and claimed in PCT International Application No. \*\*\* filed on \*\*\* and as amended under PCT Article 19 on \*\*\* (if any).

I hereby state that I have reviewed and understood the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose all information known to be material to the patentability of any claim in accordance with 37 C.F.R. § 1.56, and which is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign applications(s) for patent or inventor's certificate, or § 365(a) of any PCT International Application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's certificate, or any PCT International Application having a filing date before that of the application on which priority is claimed.

PRIOR FOREIGN APPLICATION(S)

NONE

This declaration is of the following type:

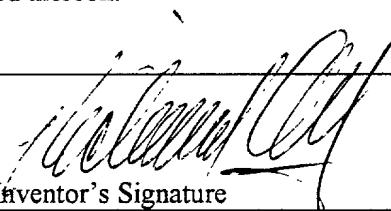
- (X) original  
( ) divisional  
( ) continuation  
( ) continuation-in-part (CIP)

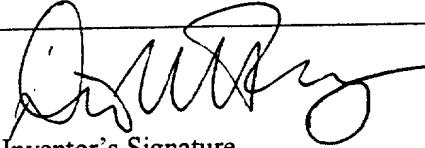
I hereby claim benefit under 35 U.S.C. § 120 of any United States application(s), or § 365(c) of any PCT International Application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided for by 35 U.S.C. § 112, first paragraph, I acknowledge the duty to disclose material information as defined in 37 C.F.R. § 1.56 which occurred between the filing date(s) of the prior application(s) and the national or PCT International filing date of this application.

PRIOR DOMESTIC APPLICATIONS

NONE

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1	Richard C. Vogel  Full Name	 Inventor's Signature	7/30/97  Date
	San Antonio, Texas U.S.A.  Residence		U.S.A.  Citizenship
	15614 Mission Crest San Antonio, Texas 78232 U.S.A.  Post Office Address		

2	David M. Tumey Full Name	 Inventor's Signature	7/29/97 Date
	San Antonio, Texas U.S.A. Residence		U.S.A. Citizenship
	5018 Newcastle Lane San Antonio, Texas 78246 U.S.A. Post Office Address		

3	Susan P. Morris Full Name	 Inventor's Signature	7/29/97 Date
	San Antonio, Texas U.S.A. Residence		U.S.A. Citizenship
	2910 Oak Fall San Antonio, Texas 78231 U.S.A. Post Office Address		

4	L. Tab Randolph Full Name	 Inventor's Signature	Date 7/29/97
	San Antonio, Texas U.S.A. Residence		U.S.A. Citizenship
	Bowl LTR 7/29/97 27917 Vena Mountain San Antonio, Texas 78260 U.S.A. Post Office Address		

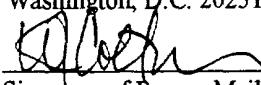
CERTIFICATE OF MAILING BY "EXPRESS MAIL" 37 C.F.R. § 1.10

"Express Mail" Mailing Label No: EH256068273US

Date of Deposit: July 30, 1997

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

07/30/97  
Date:

  
Signature of Person Mailing

Wayne J. Colton  
Printed Name of Person Mailing